

REMARKS

This paper is responsive to the Office Action mailed February 23, 2006. Claims 1-31¹ are pending in the application.

Status of claims 5, 10-21 and 29

The "Office Action Summary" page of the Office Action indicates that claims 1-30 [31?] were rejected. However, upon reviewing the "Detailed Action" portion of the Office Action, Applicants' representative is unable to find any support for, or even any discussion of, the rejection of claims 5, 10-21 and 29. For the following reasons, Applicants' representative assumes that the inclusion of these claims as "rejected" on the Office Action Summary page was an oversight, and that these claims are either allowed, or contain allowable subject matter, as more fully discussed below.

In the first substantive Office Action in this matter dated May 4, 2005, claims 5, 10-21 and 29 were indicated as including allowable subject matter. Specifically, claims 12-21 were allowed, and claims 5, 10, 11 and 29 were objected to in present form, but were indicated as containing allowable subject matter. On August 4, 2005, Applicants timely responded to the Office Action by providing arguments that all claims 1-31 were properly allowable. Subsequently, on October 31, 2005, the Examiner reconsidered his earlier action, and withdrew the previous claim rejections. In place of the earlier examination, the Examiner imposed various restriction and election requirements of all claims. According to the Examiner, the claims comprised three separate distinct inventions. Furthermore, the claims relating to one of the three inventions comprise two separate species. On November 29, 2005, Applicants timely responded to the Restriction/Election requirements. Specific arguments were presented to traverse the election requirement.

Following receipt and consideration of Applicants' response to the Restriction/Election requirements, the Office Action responded to herein was mailed from the Patent and Trademark Office on February 23, 2006. As stated in the Office Action, the election/restriction requirement had been reconsidered and withdrawn, and that all claims would be examined. As stated above, all claims 1-30 [31?] were indicated as rejected.

¹ Claims 1-31 are pending in the application, not claims 1-30 as indicated in the Office Action.

Upon review of the "Detailed Action" section of the Office Action, Applicants' representative noticed that the Office Action provided specific grounds only for the rejection of claims 1-4, 6-9, 22-28, 30 and 31. No reasons were provided for the inclusion of claims 5, 10-21 and 29 in the list of rejected claims, nor did these claims appear to be referenced or discussed in any other fashion in the Office Action. Applicants' representative has observed that the grounds cited for rejection of claims 1-4, 6-9, 22-28, 30 and 31 were essentially the same as grounds that were previously cited in the Office Action of May 4, 2005. Although a legal basis for the rejections was changed from Sec. 102(b) to 103(a), the explanation that accompanied the rejections was virtually unchanged from that in the earlier Action. There being no discussion of claims 5, 10-21 and 29, Applicants must assume that the status of these claims is the same as it was in the May 4 action, namely, that claims 5, 10, 11 and 29 were objected to, and that claims 12-21 were allowed, as in the previous action. The response provided herein is based upon that assumption. If Applicants' assumption is incorrect, the Examiner is respectfully requested to clarify the status of these claims in a subsequent non-final Office Action.

Rejections in view of the prior art

In the Office Action, Claims 1, 2, 3, 8, 9, 22 and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hazard (USP 5,058,580). Claims 4, 6, 7, 23-28 and 31 were rejected under 35 U.S.C. § 103 as being unpatentable over Hazard in view of Roy (USP 6,135,110).

A. Section 103(a) rejections over Hazard.

Claim 1 of the present application is directed to a tracheostomy tube comprising a hollow tubular body having a proximal end portion, a distal end portion and a curved portion intermediate said proximal and distal end portions. A flange is situated at the proximal end portion of the tracheostomy tube. The flange is capable of radial extension from the tube, and is manipulatable to selectively prevent said radial extension.

The Hazard patent is directed to a tracheostomy tube comprising a tubular cannula having a tapered distal end portion that forms a smooth transition insertion area. The distal end portion is beveled at one side to facilitate percutaneous insertion

of the tracheostomy tube into a patient's trachea through a stoma in the neck between adjacent cartilages. The proximal end portion of the tube includes an integrally molded flexible neck flange 26. Flange 26 is used in conjunction with apertures 27 and a suitable strap to secure the tracheostomy tube 10 through the neck of the patient. The proximal end portion 16 also includes a 15 mm standard coupler 28 adapted to readily interconnect the tracheostomy tube to a respirator system. See, Col. 4, lines 43-50.

In support of the 103(a) rejection in view of the Hazard patent, the Examiner stated that Hazard teaches a flange that is capable of radial extension, and that is manipulatable to selectively prevent radial extension. The Examiner further stated that the flange has two end extensions (near reference object 27 in Fig. 1), that are capable of preventing radial extension.

In response, Applicants respectfully submit that the flange as depicted in Hazard is expressly stated as being integral with the proximal end of the tube (Col. 4, line 44). It is not selectively manipulatable to prevent a radial extension in the manner of the flange described in the present claim. As stated in the present application, (see, e.g., paragraphs [0031] and [0032]), the flange of the inventive tracheostomy tube may be manipulated, such as by selectively removing the flange from the tracheostomy tube (see, e.g., Figs. 3 and 4), or by axially folding the flange against the body of the tube, so as not to hinder withdrawal of the introducer sheath. A tracheostomy tube having a removable or foldable flange has a reduced effective diameter when compared to conventional tracheostomy tubes that have integral radially extending flanges, such as flange 26 in the Hazard patent. As a result, an introducer sheath can be readily withdrawn in an axial direction over a tracheostomy tube in which the flange has either been removed altogether from the sheath, or otherwise folded into a position such that it does not obstruct withdrawal of the introducer sheath.

With respect to claim 2, the Examiner stated that the flange of Hazard is selectively attachable to the proximal portion to provide radial extension, and detachable "by removing a strap holding the flange to the tube " and has cited a portion of the patent specification (Col. 4, lines 48-50) in support. Applicants respectfully submit that the strap does not hold the flange to the tube, as stated by the Examiner, because the flange is integrally molded with the tube (Col. 4, line 44).

Rather, the strap is used to secure the tracheostomy tube to the patient. Nothing in the Hazard patent teaches or suggests a flange that is selectively attachable to and detachable from the proximal portion of the tube. The portion of the Hazard patent cited by the Examiner has nothing to do a removable flange. Rather, said portion (Col. 4, lines 48-50) refers to a coupler 28 that is used to interconnect the tracheostomy tube to a respirator. It is unclear to Applicants how this passage can be construed to teach a removable flange. If the Examiner continues to assert that this feature is taught by the passage in the Hazard patent, further explanation and clarification is respectfully requested.

Claim 3 is dependent on claim 2, and includes the additional limitation that the flange is attachable to the tube by a snap-fit. In the Office Action, the Examiner stated that "Hazard's disclosure of a flange with a strap attachment is considered an equivalent structure capable of securing the flange to the tube." However, as stated previously, the Hazard flange is integrally molded with the tube. The strap described in Hazard is provided to strap the tracheostomy tube to the patient's neck. It does *not* secure the flange to the tube in the manner of the snap-fit of the present claim.

Independent claim 22 is directed to a device for percutaneous insertion into the trachea of a patient comprising a tracheostomy tube having a longitudinal passageway therethrough. The distal end portion of the tracheostomy tube is percutaneously insertable into the trachea, and a proximal end portion is exterior to the trachea when the distal end portion is inserted. The tracheostomy tube further has a radially extending flange attachable to the proximal end portion of the tracheostomy tube after the distal end portion has been inserted into the trachea. A dilator is positionable within the longitudinal passageway of the tracheostomy tube for dilating an opening in the trachea. A locking assembly is provided for locking the tracheostomy tube to the dilator during insertion of said tracheostomy tube into the trachea.

First, Applicants submit that Hazard does not teach or suggest an arrangement wherein the tracheostomy tube has a radially extending flange attachable to the proximal end portion of the tracheostomy tube after the distal end portion has been inserted into the trachea. Rather, as stated, the flange in Hazard is integral with the tracheostomy tube. It is not added, and cannot be added, after the distal end portion has been inserted into the trachea.

Secondly, the Examiner stated that the Hazard device includes a locking assembly for locking the tracheostomy tube to the dilator during insertion of the tube into the trachea. In support thereof, he cited reference object 37 in Fig. 1, and Col. 5, lines 20-25 of the specification. Upon review of the pertinent portions of the Hazard patent, Applicants respectfully dispute the characterization of reference object 37 as a "locking assembly", and the depictions in the patent specification as referring to such an assembly. Reference object 37 merely refers to a flange portion that limits the depth to which the obturator can be inserted. There is no apparent locking action. In the present application, on the other hand, an actual locking assembly is provided. The locking assembly is discussed, among others, at paragraphs [0041] to [0044], and illustrated at Figs. 7-9. In the preferred embodiment shown, the locking mechanism comprises a stop mechanism 72, and a securement member 74 that engages with the stop mechanism. As illustrated, the stop mechanism is preferably an annular ring, and the stop mechanism is preferably a rotatable securement cap. In the embodiment shown, the securement member includes screw threads or other attachment mechanism for locking the securement member to a complementary attachment site on the tracheostomy tube, such as collar 22. Thus, there is an actual "locking" action that takes place in the inventive device. No such action is observed in the cited portions of the Hazard disclosure, nor does there appear to be any suggestion of providing such action. If upon consideration of Applicants' Remarks herein, the Examiner maintains this rejection, the Examiner is respectfully requested to clarify the basis upon which object 37 is considered a locking mechanism for locking the tracheostomy tube to the dilator during insertion of the tracheostomy tube into the trachea, so that Applicants may have a clear basis from which they can formulate an appropriate response.

Claim 30 was also listed as subject to the 103(a) rejection as being unpatentable over Hazard. However, this claim was not further discussed in the "Detailed Action", and no express basis for the rejection was provided in the Office Action. Nonetheless, in an attempt to move the case forward, Applicants will address the features of this claim in view of the teachings of Hazard as previously applied by the Examiner to other claims. If the Examiner has additional (although unstated) reasons upon which Hazard was applied, the Examiner is requested to apply them in a subsequent non-final action.

Independent claim 30 is directed to a method of inserting a tracheostomy tube into the trachea of a patient. The method comprises the steps of providing a tracheostomy tube comprising a hollow tubular body having a longitudinal passageway therethrough, said tubular body having a distal end portion for insertion into the trachea, and a proximal end portion exterior to the trachea when the distal end portion is inserted, said tubular body further having a curved portion intermediate said proximal and distal end portions; inserting said distal end portion of said tubular body into said trachea; trimming an excess portion of said proximal end portion of said tubular body; and engaging a flange with said tracheostomy tube at said proximal end portion of said tubular body. Applicants assert that at a minimum, Hazard does not teach or suggest the "trimming" and the "engaging" steps of the present claims. In view of the clear inapplicability of the Hazard reference to this claim, Applicants assume that the reference to claim 30 in the Office Action was likely inadvertent. Therefore, no further comments are offered on this possible rejection.

B. Sec. 103(a) rejections over Hazard in view of Roy.

Claim 4 is dependent on claim 3, and includes the further limitations that the hollow tubular body includes a collar at its proximal end, said collar having a groove, and wherein the flange includes a cut-away portion, wherein the cut-away portion and said groove are cooperatively sized and shaped to mate when the flange is attached to the tube. Since claim 4 is dependent on claim 3, it includes all the limitations of claim 3 including the limitation regarding a flange attachable to the tube by a snap-fit. The cited references, either individually or in combination, fail to teach or suggest this arrangement.

Claim 6 is dependent on claim 4, and includes the further limitation that the collar is integral with the hollow tubular body. Claim 7 is also dependent on claim 4, and includes the further limitation that the collar includes one or more barbs for attaching the collar to the hollow tubular body. Since these claims are dependent on claim 4, they include all the limitations of claims 3 and 4 set forth above. The cited references, either individually or in combination, fail to teach or suggest this arrangement. It is further noted that the snap-fit of Roy does not relate to snapping a flange to a tracheostomy tube. Rather, Roy teaches a pressure adjusting mechanism for fixedly mating an inner cannula to an outer cannula. Further, it is

noted that the collar of Roy is coupled to the inner cannula, unlike the arrangement of the present invention wherein the collar is engaged with the tracheostomy tube.

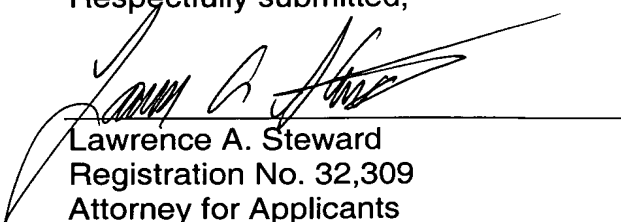
Claims 23-28 are dependent, directly or indirectly, on claim 22 and include all of its limitations, including the limitation of a locking assembly for locking the tracheostomy tube to the dilator during insertion of the tracheostomy tube. It is further noted that Roy fails to set forth a locking assembly as claimed. Accordingly, Applicants respectfully submit that the cited references, either individually or in combination, fail to teach or suggest the features of the present claims. Accordingly, Applicants submit that claims 23-28 are allowable for at least the same reasons that claim 22 is allowable.

Claim 31 is dependent on claim 30, and therefore includes all of its limitations. Applicants have reviewed the Office Action, and can find no explanation by the Examiner on the basis for the rejections of claims 30 and 31. Nonetheless, upon review of the cited references, Applicants assert that such claims are allowable over these references.

Conclusion.

For the reasons provided hereinabove, Applicants respectfully submit that all claims 1-31 are in condition for allowance. Accordingly, Applicants respectfully request the prompt issuance of a Notice of Allowance. If the Examiner believes that any disposition other than allowance of all claims is appropriate, Applicants respectfully request that such disposition be provided in a non-final Office Action so that Applicants have adequate opportunity to address any items raised by the Examiner.

Respectfully submitted,



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